

Fig. 1A

Mean rFGF Plasma Concentration Versus Time Post IC Administration

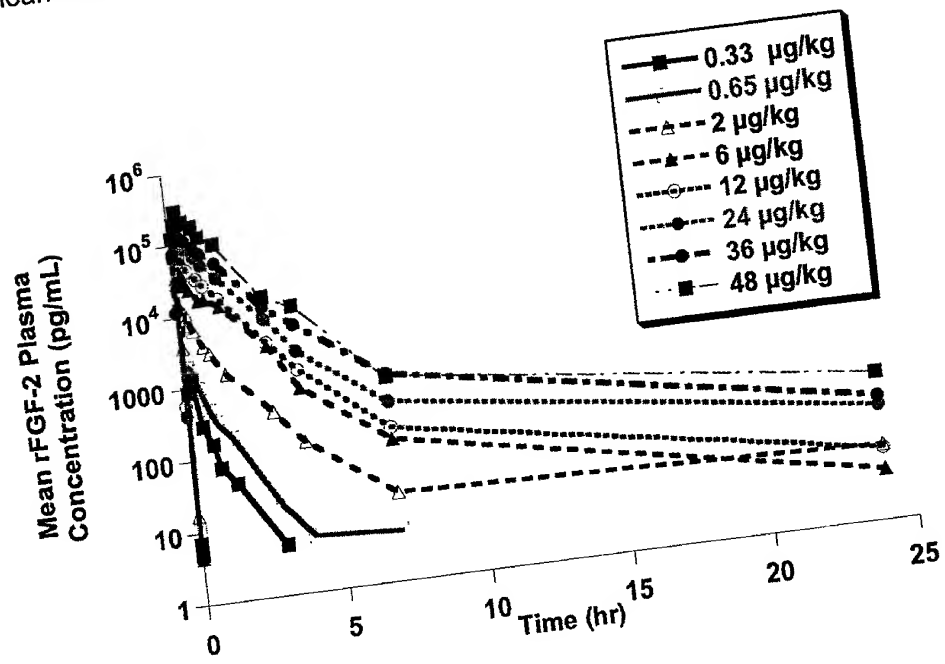


Fig. 1B

Mean rFGF-2 Plasma Concentration-Time Profiles Following IV Administration. Mean rFGF-2 Plasma Concentration Profile Following Administration of 36  $\mu\text{g/kg}$  IC Included for Comparison.

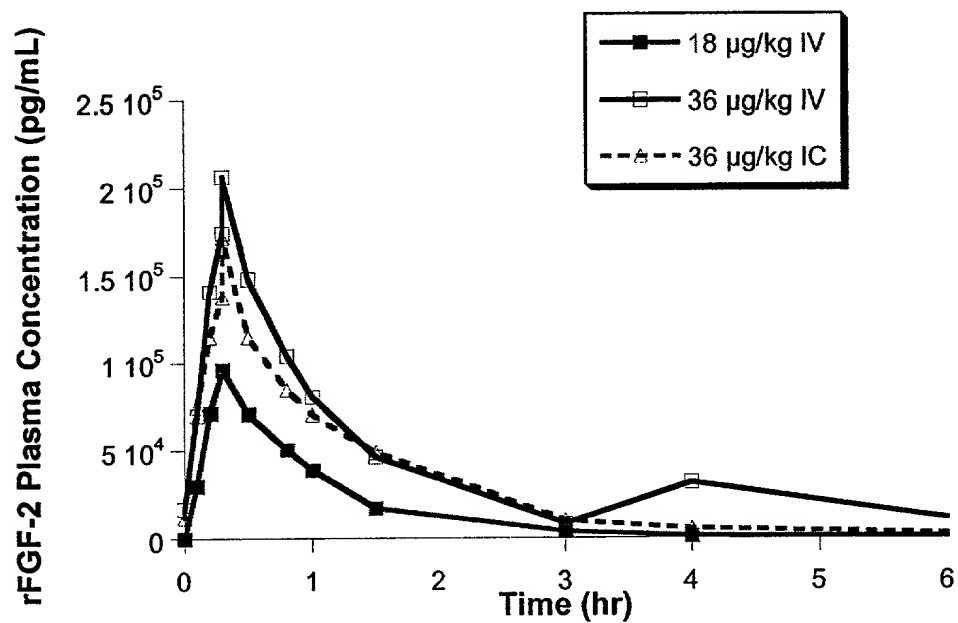


Fig. 2

Mean rFGF-2 AUC Vs Dose

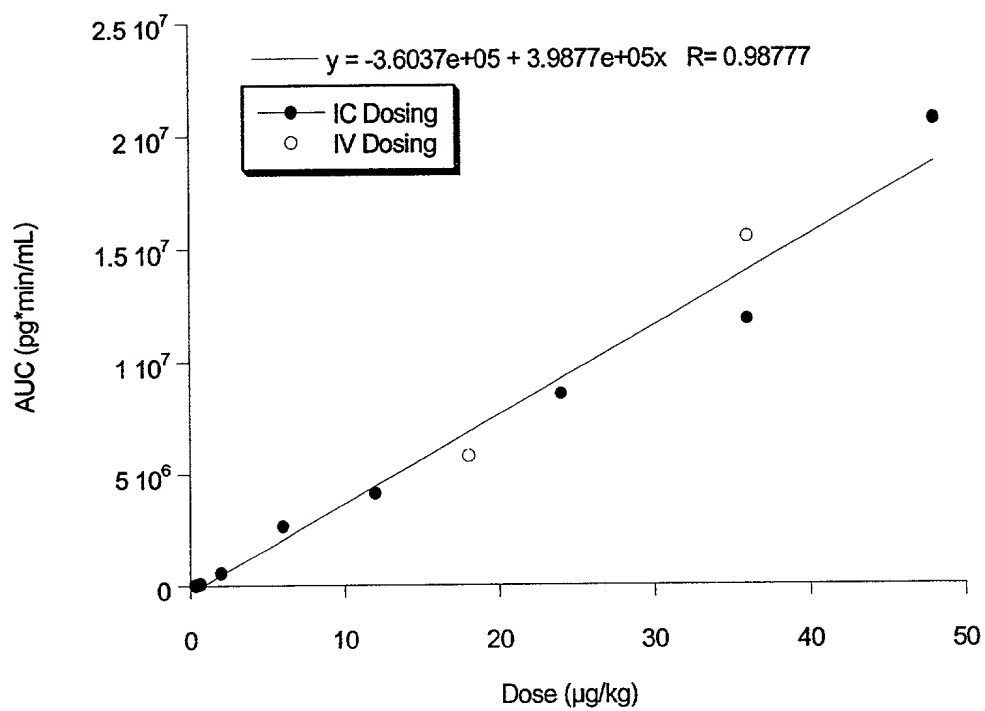


Fig. 3

Individual Patient rFGF-2 Plasma Clearance Values

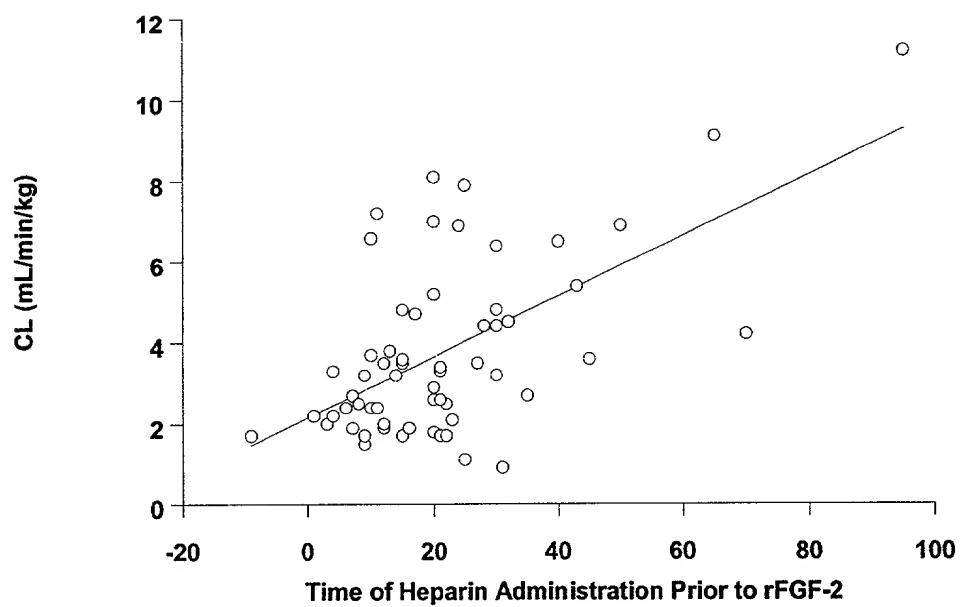
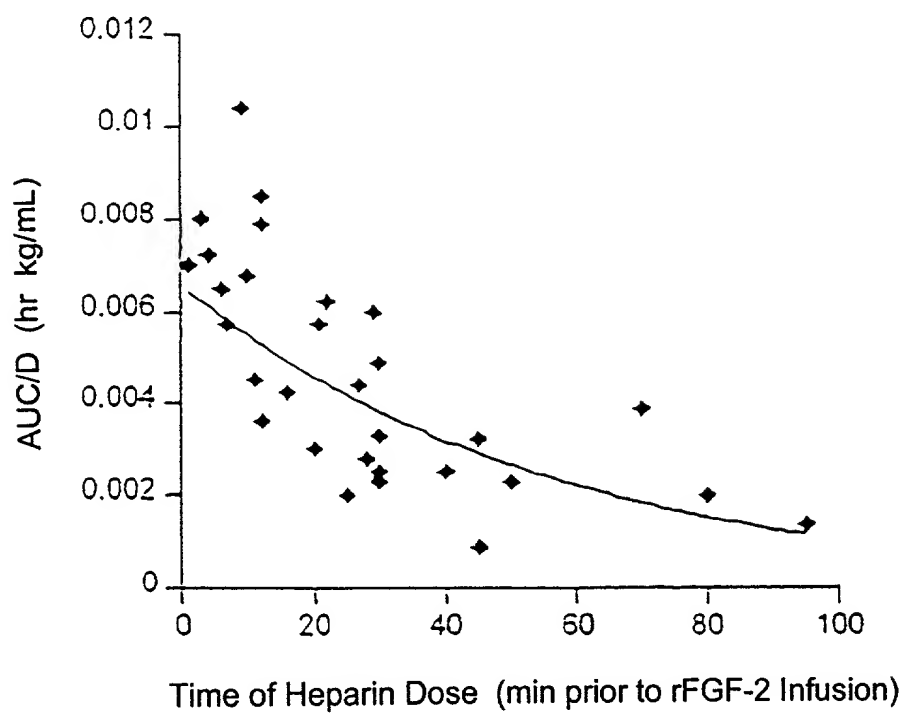


Fig. 4

Individual Patient rFGF-2 Dose-Normalized AUC Versus Dose in Study CS-FG001



# *FIRST: Analysis Plan*

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- Primary Efficacy Analysis: change in ETT at 90 days for all evaluable patients by ANOVA
  - Evaluable Patients: subjects with ETT at day 90 who were not revascularized
- Secondary Analyses:
  - ANOVA of Ranks: assigns lowest rank to patients with missing data or revascularized
  - pair-wise comparisons: each dose vs placebo, any FGF vs placebo by ANOVA and ANOVA of Ranks
- Post hoc analyses:
  - by Canadian Cardiovascular Score (CCS)
  - by angina frequency score (AFS)

# FIRST: Patient Characteristics

	rFGF-2 (ug/kg)			
	Placebo	0.3	3.0	30
Number of Subjects	82	82	82	82
Age (years)	64	63	63	62
Male sex (%)	86	84	80	86
Diabetes (%)	32	33	37	25
Dyslipidemia (%)	93	94	95	91
Hypertension (%)	77	71	68	68
Prior MI (%)	70	65	65	69
Prior CABG (%)	91	89	88	89
Prior PTCA with stent (%)	43	26	42	29
Prior PTCA w/o stent (%)	49	41	32	42
Baseline ETT time (sec)	513	527	525	514
Canadian Cardiovascular Classes II or III (%)	87	87	90	89

# FIRST: Patient Disposition

		rFGF-2 (ug/kg)			
		Placebo	0.3	3.0	30
Subjects Enrolled		86	82	84	83
Safety FU: 180 days		82	76	80	83
ETT at 90 / 180 days		82 / 75	75 / 71	79 / 74	77 / 76
Premature Withdrawal		4	6	4	2
- Death		1	1	3	1
- Adverse Event		1	2	1	0
- Withdrew Consent		1	1	0	1
- Lost to Follow-up		0	1	0	0
- Protocol Deviation / Violation		0	1	0	0
- Nonclassified		1	0	0	0
Revascularized					
Subjects Excluded from Analysis		5	5	3	6

Figure 7

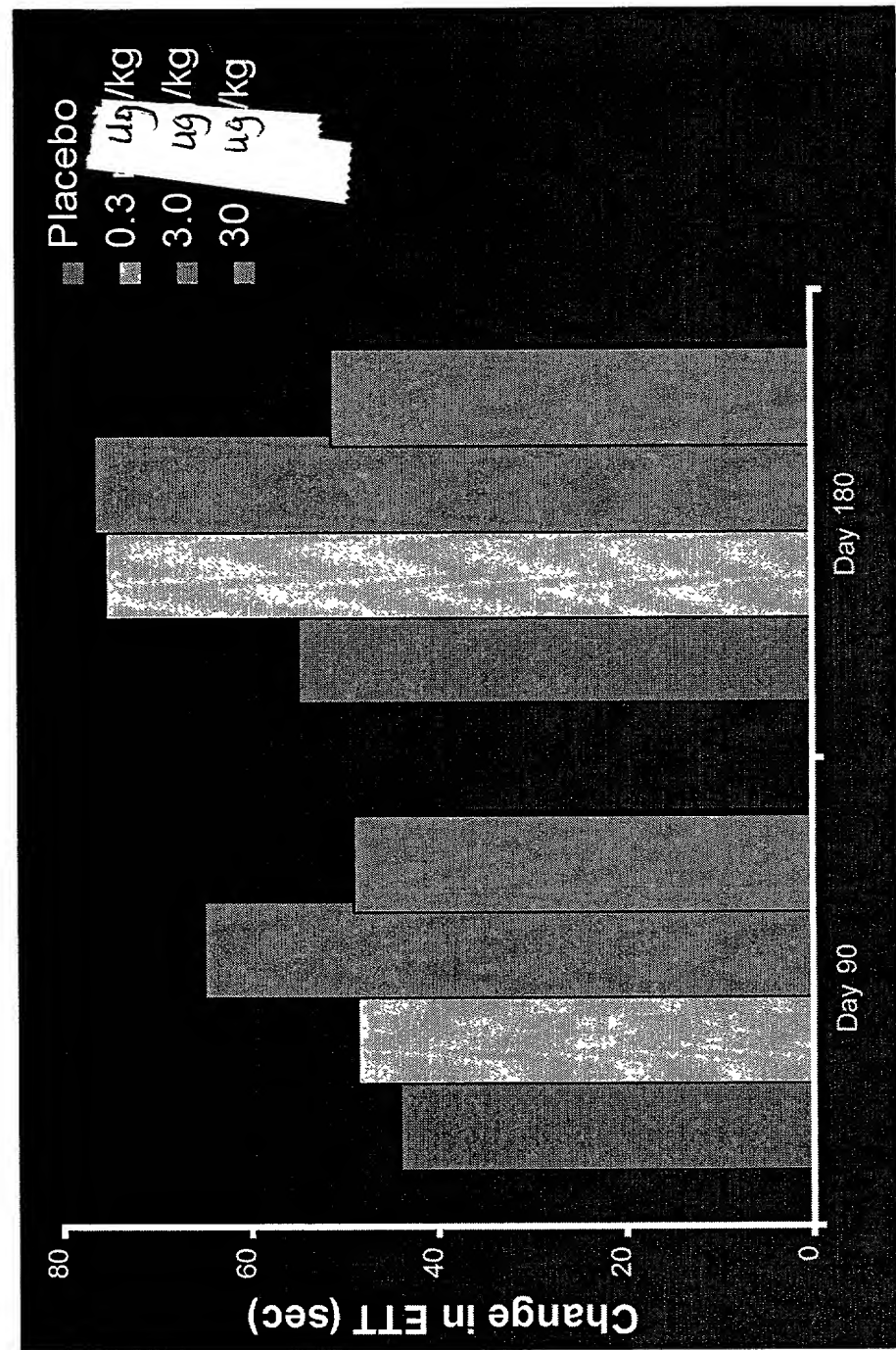


# FIRST: Safety

rFGF-2 (ug/kg)				
	Placebo	0.3	3.0	30
<b>Number of Subjects</b>	86	82	84	85
<b>All Serious Events</b>	29 (34%)	29 (35%)	22 (26%)	35 (41%)
<b>Deaths</b>	1	1	3	1
<b>Carcinoma</b>	1	0	1	1
<b>Cardiac Events</b>				
Admissions for	18	12	8	21
Angina/Chest Pain				
Cardiac Arrest	0	1	2	1
Myocardial Infarct	5	2	5	5
Revascularizations	5	5	3	6
<b>Laboratory Findings</b>				
Clearance: < 60 mL/min	4	0	1	3
Creatinine > 2.5 mg/dL			None	
Proteinuria: > 300 mg/24 h	4	5	4	5

# Change in Exercise Time

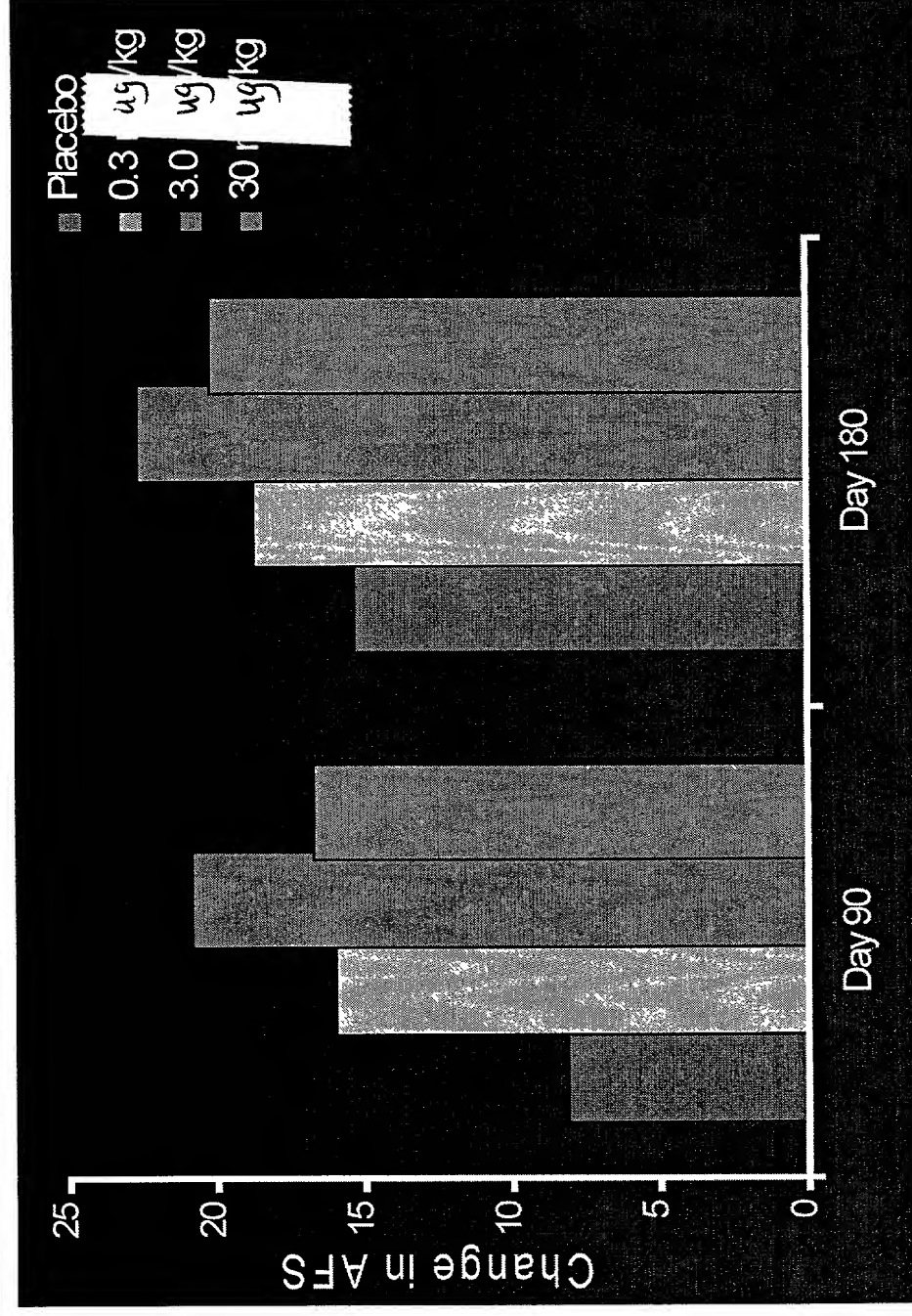
# Primary Efficacy Analysis at Day 90: overall $p = .64$



Day 180: overall  $p = 0.44$

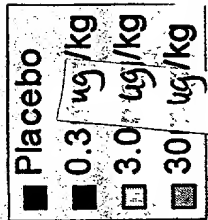
### Revascularized subjects and subjects with missing ETT excluded

# Change in Angina Frequency Score



Day 90: overall  $p = 0.035^*$       *Revascularized subjects and*  
 Day 180: overall  $p = 0.38$       *subjects with no data excluded*





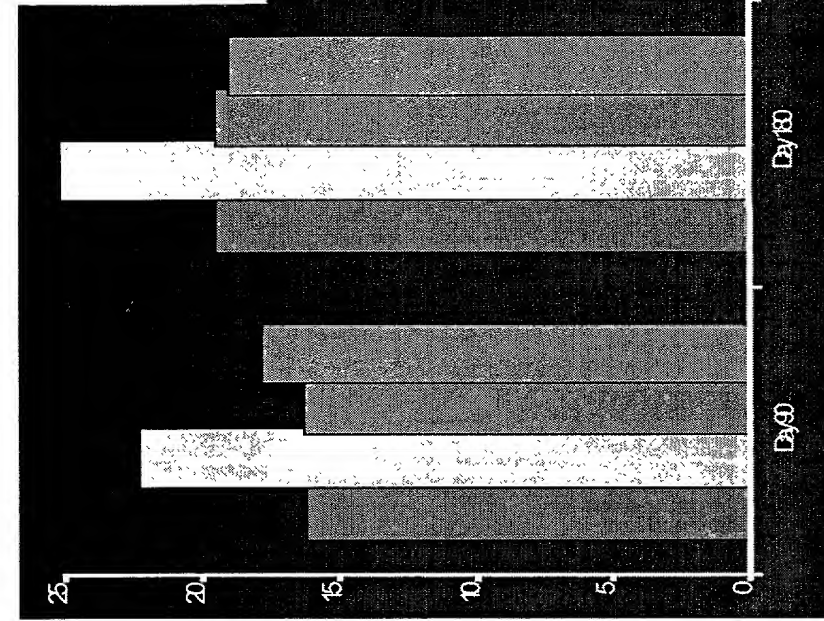
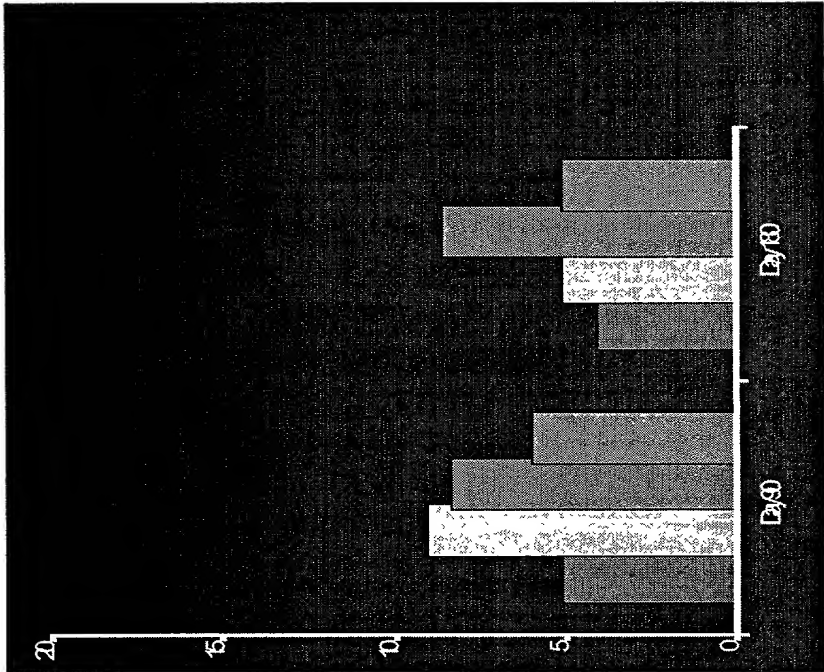
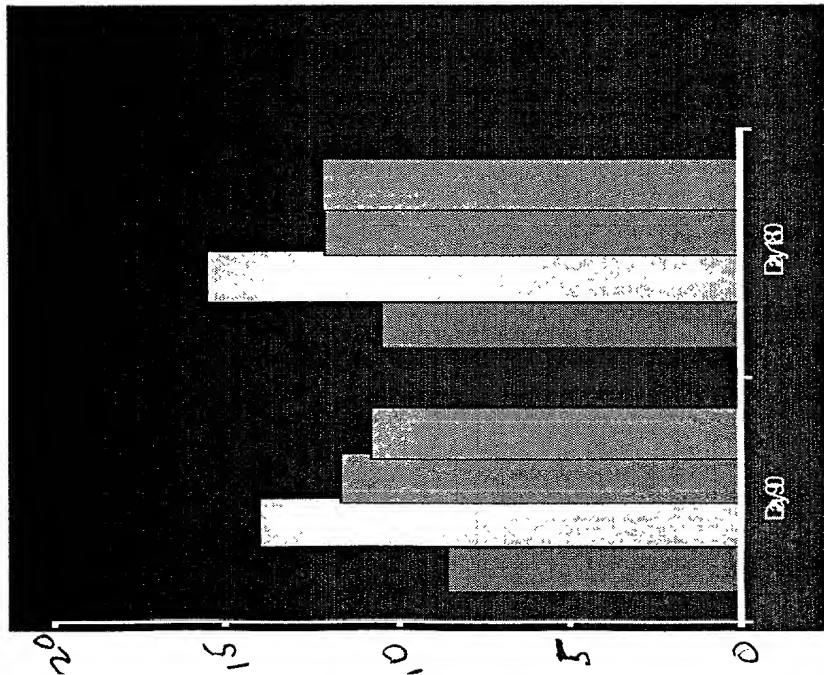
# Seattle Angina Questionnaire

## Change in Other Domains

Exertional Capacity

Treatment Satisfaction

Disease Perception



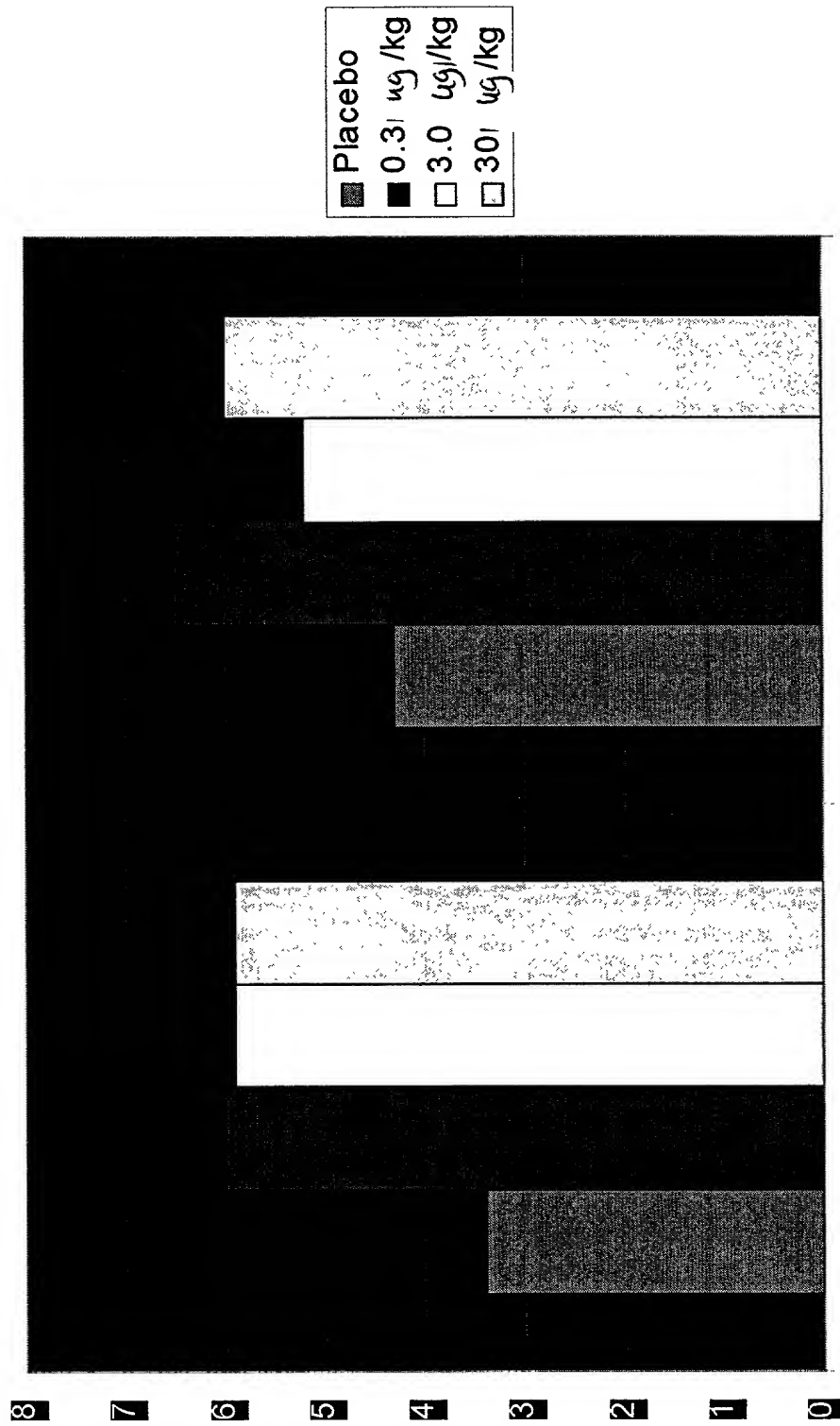
All P values > .05

Revascularized subjects and  
subjects with no data excluded

Figure 11  
Placebo  
0.3 ug/kg  
3.0 ug/kg  
30 ug/kg

# Change in Short Form-36

## *Change in Physical Component Summary Score*



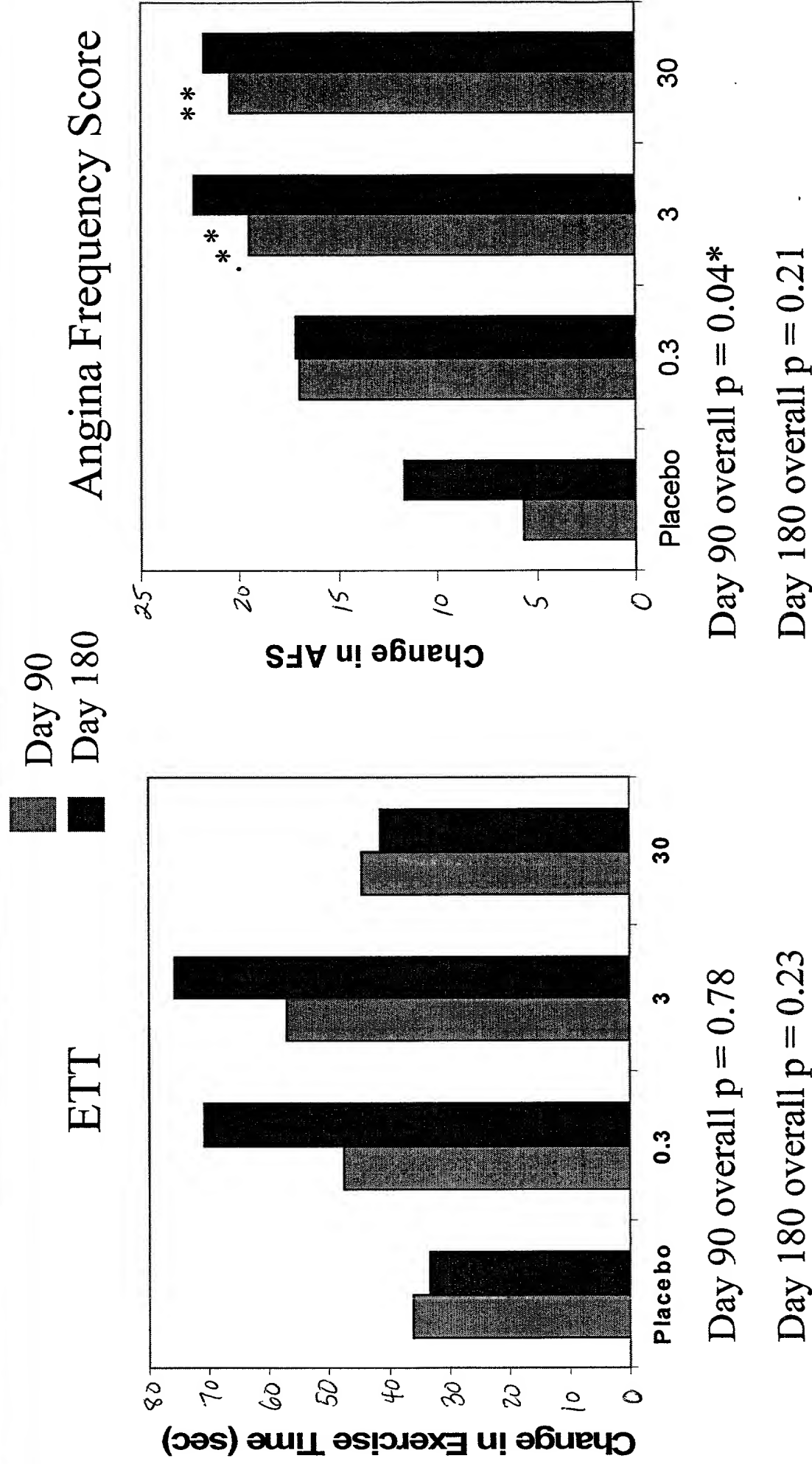
Day 90 overall  $p = .21$   
 $p = .033$  for All FGF

Day 180  
*Revascularized subjects and subjects with no data excluded*

Figure 12

Figure 13

# Stratified by Baseline CCS Class 3 or 4



# Stratified by Baseline AFS $\leq 40$

